

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S

Plaintiff,

V.

ACAMBIS INC. and  
ACAMBIS PLC,

Defendants.

C.A. No. 05-614-SLR

**BAVARIAN NORDIC'S ANSWERING BRIEF  
IN OPPOSITION TO ACAMBIS' MOTION FOR LEAVE  
TO FILE AMENDED ANSWER AND COUNTERCLAIMS**

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## INTRODUCTION AND NATURE AND STAGE OF THE PROCEEDINGS

Bavarian Nordic A/S (“Bavarian Nordic”), a leading developer and producer of vaccines and related products that prevent and treat infectious diseases, brought this suit alleging that Acambis Inc. and Acambis, PLC (“Acambis”) have committed acts of unfair trade practices, tortious conversion, misappropriation of trade secrets in violation of state laws, and unfair competition under the Lanham Act. Bavarian Nordic has also brought suit against Acambis at the International Trade Commission (“ITC”) alleging patent infringement and unfair acts in the importation of goods. Non patent claims in the ITC proceeding have been dismissed without prejudice and a hearing was conducted in the case from May 8 through May 15, 2006. Motions for summary determination on patent issues were denied, including Acambis’ motion for summary determination on invalidity with respect to U.S. Patents Nos. 6,761,893 and 6,913,752. An initial determination from the ITC is expected in August.

Acambis answered the Complaint in this case without alleging any counterclaims and moved to stay this proceeding pursuant to 28 U.S.C. § 1659(a). The motion to stay has not been decided and Acambis has not withdrawn its motion, though Bavarian Nordic has brought to the Court's attention the mootness of the motion based on the elimination of non-patent claims from the ITC proceeding.

Now, nine months after the filing of the complaint in this case, after the close of document discovery, and four months after the close of fact discovery at the ITC in February, Acambis seeks to add seven counterclaims, including discovery intensive antitrust counterclaims, each based on patents which are not involved in this proceeding. Because the delay in bringing these unrelated counterclaims is unwarranted and

prejudicial, and because the counterclaims are futile, Acambis' motion for leave should be summarily denied.

### SUMMARY OF ARGUMENT

1. In its motion for leave to amend, Acambis seeks to add seven new counterclaims: two declaratory judgment counterclaims that two of Bavarian Nordic patents are invalid and unenforceable; antitrust counterclaims alleging Walker Process and “sham” litigation type claims; and various competition torts. There is no justification for such a large expansion of this case nine months after the filing of the complaint and after the close of document discovery. The delay in bringing these claims is unfairly prejudicial to Bavarian Nordic and, if they are added, would result in the schedule of this case being significantly extended.

2. Acambis' declaratory judgment counterclaims are futile. Acambis in its amended answer alleges, and discovery in this case has shown, that Acambis is a government contractor that has only made, used or sold MVA3000 vaccine by or for the US Government. But, pursuant to 28 U.S.C. § 1498, a patent owner's remedy for patent infringement by a government contractor is not in District Court. Rather, “the owner's remedy shall be by action against the United States in the Court of Federal Claims.” Thus, no actual controversy “within the court's jurisdiction” exists pursuant to 28 U.S.C. § 2201 to give rise to declaratory judgment jurisdiction. Moreover, a declaratory judgment action should not go forward where a special statutory proceeding has been provided, such as the § 1498 proceeding. *See* FED. R. CIV. P. 57; *Katzenbach v. McClung*, 379 U.S. 294 (1964).

3. Acambis' antitrust counterclaims are futile as Acambis does not and cannot allege antitrust injury and cannot show that it has antitrust standing. In this regard, the basis for Acambis' antitrust counterclaims is that Bavarian Nordic's enforcement of its patents and litigation against Acambis constitutes Walker Process and "sham" litigation. However, Acambis cannot and does not allege any pre-enforcement harm, and there is none. With respect to post enforcement harm, there is also none, as the government has yet to award any contracts after the initiation of this and the ITC lawsuit. Thus, there has been no antitrust injury to date. Moreover, Acambis has not even alleged that there is a dangerous probability that Bavarian Nordic will succeed in monopolizing the market, and thus Acambis lacks standing for this reason as well. Thus, under well-settled Third Circuit case law, Acambis' antitrust counterclaims do not state a cause of action and are futile.

4. Acambis' remaining claims, in addition to being tardy, are futile for largely the same reasons that the antitrust claims are futile. Acambis has not suffered any injury in selling MVA3000 to the Government pursuant to RFP-1 and RFP-2. To the contrary, Acambis has received awards pursuant to RFP-1 and RFP-2. Any such injury, if it existed, could have been plead in the original answer. There has been no contract award since the filing of the lawsuit, and thus Acambis has sustained no injury from alleged tortious interference or advertising to the government. In fact, in RFP-3, the government omitted any requirement that the bidders indicate that they have freedom to operate. Thus, the crux of Acambis' remaining allegations – that Bavarian Nordic's claims that its intellectual property is being used without authorization by Acambis – is irrelevant to Acambis' ability to sell MVA3000 to its only customer.

### STATEMENT OF FACTS

Bavarian Nordic alleges four counts in the Delaware Complaint: (1) tortious conversion; (2) misappropriation of trade secrets pursuant to 6 Del. C. § 2001 *et seq.*; (3) unfair trade practices pursuant to 6 Del. C. §2531 *et seq.* and Delaware common law; and (4) unfair competition under the Lanham Act, 15 U.S.C. § 1125(a). Bavarian Nordic has not alleged infringement of any U.S. Patents in this case.

It is undisputed (and indeed Acambis alleges) that Acambis' MVA3000, a small pox vaccine which forms the basis for Bavarian Nordic's claims in this action, has not received FDA approval. (Proposed Answer, Counterclaim ("CC") ¶ 7). Thus, the U.S. Government is Acambis' only customer for MVA3000.

In September 2002, The US Government released a first Request For Proposal ("RFP-1") for an MVA-based small pox vaccine. (Proposed Answer, CC ¶ 16). In February 2003, the US Government awarded contracts to both Bavarian Nordic and Acambis for the development of MVA-based small pox vaccines pursuant to RFP-1. *Id.* The US Government subsequently released RFP-2 for the continued development of MVA-based small pox vaccines and again awarded contracts to both Bavarian Nordic and Acambis and Bavarian Nordic in September 2004. (Proposed Answer, CC ¶ 17). The US Government released RFP-3 for the manufacture and delivery of 10-20 million doses of MVA-based small pox vaccines on August 15, 2005. (Proposed Answer, CC ¶¶ 18, 19). Both Bavarian Nordic and Acambis have submitted proposals in response to RFP-3, but it is unclear when there will be an award. (Proposed Answer, CC ¶¶ 20).

For its antitrust counterclaims, Acambis does not allege that Bavarian Nordic has a dangerous probability of success in monopolizing a relevant antitrust market. *See*



Proposed Answer at CC ¶¶ 60 – 68 for the Walker Process counterclaim and CC ¶¶ 69 – 74 for the “sham” litigation counterclaim.

### ARGUMENT

As explained in detail below, there is no basis for granting the broad motion for leave to amend that Acambis requests.

#### **I. Rule 15 Does Not Permit Dilatory Amendments Wholly Unrelated to the Original Case**

In its motion to Amend, Acambis seeks leave to amend its answer under either Rule 15(a) or 15(d) (without distinguishing), principally to add seven counterclaims to the case, all of which relate to patents on which Bavarian Nordic has not sued Acambis in this Court. None of the counterclaims was part of Acambis' original answer served approximately nine months ago, although they could have been. And, none relate to the allegations of trade secret misappropriation, conversion and Lanham Act claims that Bavarian Nordic's has brought in this case.

Acambis seeks to justify the addition of these claims by citing to both Rule 15(a) and (d) and cases applying the rules, emphasizing that such amendments are “freely granted” and “liberally granted” to permit, for example, as complete an adjudication as possible between the parties. Acambis also suggests that the Court has “limited discretion” to deny a Rule 15 amendment. But, Rule 15 does not suggest that causes of action wholly unrelated to the original action – such as the antitrust, patent infringement and invalidity counterclaims in this case – may be added at any point in a litigation. Rather, Rule 15 requires written consent of the adverse party or leave of court and a showing that “justice so requires.” The U.S. Supreme Court, in *Foman v. Davis*, 371 U.S. 178, 182 (1962), has held that a motion to amend must ordinarily be granted in the

absence of “undue delay, bad faith or dilatory motive on part of the movant . . . undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of [the] amendment.”

The Third Circuit has endorsed a three-factor test for determining whether a delay results in prejudice to a nonmoving party: “whether the assertion of the new claim would: (i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004) (quoting *Block v. First Blood Assocs.*, 988 F.2d 344 (2d Cir. 1993)).

The first two *Long* factors are relevant and present in the instant case. Acambis' counterclaims, in particular its Antitrust counterclaims and various other competition claims would require significant additional discovery into the definition of relevant small pox markets as reflected in Acambis' and third party documents, Acambis' prospective economic prospects and other issues. These areas of discovery, particularly for the antitrust counterclaims, are notoriously complex, time consuming and costly. These areas of discovery are also outside of the scope of Bavarian Nordic's complaint for trade secret misappropriation, conversion and Lanham Act violations. Thus, it is apparent that several of Acambis' new counterclaims would represent a wholesale expansion of the case and require Bavarian Nordic to expend significant additional resources to “conduct discovery and prepare for trial.”

The second *Long* factor is also present. Acambis' nine month delay in bringing its new counterclaims brings them into the case after the close of document discovery, but

with time remaining for fact discovery. If Acambis' motion is granted, the schedule for this case would have to be extended to allow Bavarian Nordic to take additional document discovery and to allow sufficient time to take follow up depositions and discovery based on documents uncovered. This would, of necessity, add several months to the schedule in this case. Thus, both *Long* factor for undue delay are presented by Acambis' proposed counterclaims.

## **II. Acambis' New Counterclaims Unduly Prejudice Bavarian Nordic**

Acambis' new counterclaims prejudice Bavarian Nordic in two ways. First, having delayed nine months in bringing the counterclaims, Acambis has denied Bavarian Nordic months of discovery and has presented them after the close of document discovery. Thus, the new claims, particularly the antitrust counterclaims, would deny Bavarian Nordic an opportunity to conduct sufficient document discovery and follow up discovery within the present schedule of the case. Second, if the schedule of the case is extended to permit Acambis to add its counterclaims and to permit Bavarian Nordic to conduct follow up discovery, Bavarian Nordic will be prejudiced by having its original claims watered down by the inclusion of unrelated antitrust and patent claims that will have a tendency to greatly increase the complexity of the case and confuse a jury. Moreover, additional delay in the adjudication of the merits of this case work to the detriment of Bavarian Nordic, which seeks to have its rights vindicated. Acambis' strategy, first with its motion to stay that it never withdrew and now with its efforts to add wholly unrelated claims, is designed to delay resolution of Bavarian Nordic's claims. Perhaps Acambis' strategy to add patent claims is a ploy to try to force an additional lawsuit against the U.S. Government in the midst of a bidding process involving Acambis

and Bavarian Nordic. In either case, the counterclaims are unfairly prejudicial to Bavarian Nordic and should not be allowed.

### **III. Acambis' Counterclaims Are Futile**

Acambis has brought seven counterclaims, all related to patents that are not the subject of this proceeding. In addition to their tardy and prejudicial presentation, each of the counterclaims is futile and without foundation.

#### **A. Acambis' Declaratory Judgment Counterclaims Are Futile**

The first and second counterclaims are for declaratory judgment to have two Bavarian Nordic patents declared invalid. But, this Court lacks jurisdiction to hear such claims. The plain language of the Declaratory Judgment Act set forth in 28 U.S.C. § 2201 requires a court to find an "actual controversy within its jurisdiction." 28 U.S.C. § 2201. To satisfy the actual controversy requirement for a declaratory judgment in patent cases, there are two requirements that generally must be met by a plaintiff. First, there must be an actual or implicit charge of infringement to put the plaintiff under a reasonable apprehension that the patent owner will enforce its patent rights. Second, the plaintiff must have actually produced or is prepared to produce the allegedly infringing goods. *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631, 634 (Fed. Cir. 1991); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987)).

In this case, Bavarian Nordic's rights to bring suit for patent infringement against Acambis in this Court are limited. This is because, the product that Bavarian Nordic alleges infringes its patents at the International Trade Commission – MVA3000 small pox vaccine – is one that Acambis alleges it has only made, used or sold for the US Government. Indeed, Acambis further alleges, and discovery at the ITC has shown, that Acambis does not have FDA approval to permit other uses of MVA3000. Under these

circumstances, pursuant to 28 U.S.C. § 1498, a patent owner's remedy for patent infringement is not in District Court. Rather, “the owner's remedy shall by action against the United States in the Court of Federal Claims.” Thus, no actual controversy “within the court's jurisdiction” exists pursuant to 28 USC § 2201 to give rise to declaratory judgment jurisdiction in this Court. Moreover, it is well established in FED. R. CIV. P. 57 and Supreme Court authority that a declaratory judgment action should not go forward where a special statutory proceeding has been provided, such as the § 1498 proceeding. *See* FED. R. CIV. P. 57; *Katzenbach v. McClung*, 379 U.S. 294 (1964). Thus, Acambis' attempt to add declaratory judgment claims for invalidity and unenforceability of patents not involved in this case is futile.

#### **B. Acambis' Antitrust Counterclaims Are Futile**

For the reasons stated below, Acambis' antitrust counterclaims are futile. Both are brought under section 2 of the Sherman Act and thus require specific showings of antitrust injury and standing in order to survive motions to dismiss. Neither counterclaim meets this high bar.

##### **1. Acambis Has Failed to Plead Antitrust Injury**

In order to prevail on a Walker Process-type antitrust counterclaim, Acambis must establish that Bavarian Nordic attempted to enforce patents that issued because Bavarian Nordic defrauded the Patent and Trademark Office; that Bavarian Nordic's attempted enforcement threatened to lessen competition in a relevant antitrust market; that Acambis suffered antitrust damages; and that all other elements of attempted monopolization are met. *See Unitherm Food Systems, Inc. v. Swift Eckrich, Inc.*, 375 F. 3d 1341, 1347 (Fed. Cir. 2004) (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S.

172, 178 (1965)). Antitrust counterclaims based on “sham” litigation also require a showing of antitrust damages. *Walker Process*, 382 U.S. 172 at 177-178. In both cases, standing to bring an antitrust counterclaim is determined by the law of the regional circuit. *Unitherm*, at 1357. While unrelated to the ensuing analysis, it is worth noting at this point that Bavarian Nordic believes that Acambis' inequitable conduct counterclaim is without merit. Also, Acambis' motion for summary determination on invalidity of the asserted patents was denied. Moreover, with respect to the “sham” litigation claim, the ITC staff attorneys have come down in favor of a finding of patent infringement on all of the asserted patent claims.

An antitrust injury (or damages) is an “injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). Thus, to allege an antitrust injury, a plaintiff must allege: (1) that the alleged injury-causing conduct reduced competition and thereby injured consumers, see, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 697-99 (E.D. Pa. 2004); and (2) that the plaintiff's injury was actually caused by the alleged anticompetitive conduct, see *Alberta Gas Chemicals Ltd. v. E.I. du Pont de Nemours & Co.*, 826 F.2d 1235, 1240 (3d Cir. 1987). An antitrust complaint that does not plead facts sufficient to show that the plaintiff has suffered antitrust injury **must be dismissed**. See, e.g., *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 265 (3d Cir. 1998) (emphasis added); *Barton & Pittinos, Inc., v. SmithKline Beecham Corp.*, 118 F.3d 178, 184 n.9 (3d Cir. 1997).

Here, Acambis does not and cannot allege antitrust injury and cannot show that it has antitrust standing. In this regard, the basis for Acambis' antitrust counterclaims is

that Bavarian Nordic's enforcement of its patents and litigation against Acambis constitutes Walker Process and “sham” litigation. However, Acambis cannot and does not allege any pre-enforcement harm, and there is none. With respect to post enforcement harm, there is also none, as the government has yet to award any contracts after the initiation of this and the ITC lawsuit. Thus, there has been no antitrust injury to date.

The only injury alleged in connection with the antitrust counterclaims is set forth in paragraph 67 of the counterclaims. However, this supposed injury is merely the cost of litigating against Bavarian Nordic, a decrease in the value of Acambis’ stock; harm to Acambis’ reputation and good will; and **“to the extent that BN’s illegal scheme is successful**, harm to Acambis’ ability to compete for, obtain and fulfill contracts offered by the U.S. Government.” (See Proposed Answer, CC ¶ 67). (Emphasis added). None of these alleged damages is an injury to competition. Rather, at most they comprise an injury to Acambis. See, e.g., *Town Sound and Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 494 n.40 (3d Cir. 1992) (*en banc*) (Even if “a certain class of competitors . . . might be doomed to competitive oblivion”, “that would be no concern of the antitrust laws unless consumers were also hurt because of diminished competition”). Thus, under well settled third circuit case law, Acambis’ antitrust counterclaims do not state a cause of action and are futile.

## 2. **Acambis Has Failed to Satisfy Other Necessary Elements of Antitrust Claims**

Acambis also has failed to satisfy the other necessary elements of antitrust counterclaims. The elements of an attempted monopolization claim are “(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent



to monopolize and (3) a dangerous probability of achieving monopoly power.” *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993); *Queen City Pizza, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 442 (3d Cir. 1997). While Acambis has failed to allege facts with respect to any of these requirements, the failure to allege a dangerous probability of achieving monopoly power is particularly fatal. Courts have repeatedly held that conclusory and unsupported allegations of “dangerous probability” are insufficient to withstand a motion to dismiss an attempted monopolization claim. *See, e.g., Brunson Communications, Inc. v. Arbitron, Inc.*, 239 F. Supp. 2d 550, 571-72 (E.D. Pa. 2002); *Fresh Made, Inc. v. Lifeway Foods, Inc.*, No. Civ. A. 01-4254, 2002 WL 31246922, at \*8 (E.D. Pa. Aug. 9, 2002); *Smith & Johnson, Inc. v. Hedaya Home Fashions Inc.*, No. 96 Civ. 5821 (MBM), 1996 U.S. Dist. LEXIS 19023, 42 U.S.P.Q.2d (BNA) 1386 (S.D.N.Y. Dec. 26, 1996). Here, Acambis does not even allege a dangerous probability of success much less facts in support of the allegation. Moreover, there is no reason to believe that RFP-3, if and when it is eventually awarded, will be different from prior precedent – a split award in effect funding two competitors.

Thus, Acambis’ antitrust counterclaims are futile, as it has failed to plead facts that establish an injury to competition, as opposed to an injury to itself. *See, e.g., Town Sound*, 959 F.2d at 494 n.40.

### **C. Acambis’ Remaining Claims Are Futile**

Acambis’ remaining claims, in addition to being tardy, are futile for largely the same reasons that the antitrust claims are futile. Acambis has not suffered any injury in selling MVA3000 to the Government pursuant to RFP-1 and RFP-2. To the contrary, Acambis has received awards pursuant to RFP-1 and RFP-2. Any such injury, if it




existed, could have been plead in the original answer. There has been no contract award since the filing of the lawsuit, and thus Acambis has sustained no injury from alleged tortious interference or advertising to the government. In fact, in RFP-3, the government omitted any requirement that the bidders indicate that they have freedom to operate. Thus, the crux of Acambis' remaining allegations – that Bavarian Nordic's claims that its intellectual property is being used without authorization by Acambis – is irrelevant to Acambis' ability to sell MVA3000 to its only customer.

### CONCLUSION

Because, as discussed above, Acambis' counterclaims are dilatory, unfairly prejudicial and futile, Acambis' motion to Amend its answer to add counterclaims should be summarily denied.

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June 6, 2006

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**CERTIFICATE OF SERVICE**

I, Karen L. Pascale, Esquire, hereby certify that on June 6, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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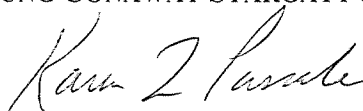
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